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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,243	10/15/2001	Juan-Carlos Diaz	P842 CIP	4113

28390 7590 11/14/2005

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IP LEGAL DEPARTMENT
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EXAMINER	
THALER, MICHAEL H	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,243	DIAZ, JUAN-CARLOS	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-10,12-22 and 25-27* is/are allowed.

6)☒ Claim(s) *1,11,23,24 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2005 has been entered.

The disclosure is objected to because of the following informalities: Reference numerals 64 and 75 are absent from the drawings. A period should be inserted at the end of claim 24. Appropriate correction is required.

Claims 1 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is unclear if the stent recited in line 25 or the stent retention portion recited in line 23 extends for at least a compressed stent length as recited in line 26.

Claims 1, 11, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler (5,817,101) in view of Luckic et al. (5,709,703) and Mager et al. (5,326,011). Fiedler, in figures 1-3, discloses catheter 22 having a guidewire lumen 24

and pressurizing lumen 26, fixed seal mount (the portion of catheter 22 which supports seal 38), sheath 36 having a movable seal mount (the portion of sheath 36 which supports seal 40), a stent retention portion of said sheath (the portion of sheath 36 which surrounds stent 50 prior to stent deployment), a stent retraction portion of said sheath (the proximal portion of sheath 36 which surrounds seal 38 prior to stent deployment), first seal structure 38 and second seal structure 40. Fiedler fails to disclose the stent retraction portion of the sheath as having an inner surface made of a material different from the material of an inner surface of the stent retention portion of the sheath. However, Luckic et al. teach that a stent containment sheath 2 should include several sections, including a scratch protection tube 18 at the distal end of the sheath in order to obtain the advantage of preventing the stent from scratching the sheath (col. 2, lines 13-60 and col. 7, lines 9-24). It would have been obvious to include a scratch protection tube in the distal end of the Fiedler sheath 36 so that it too would have this advantage. With this modification, the stent retention portion of the Fiedler sheath 36 would be made of a first material (the metal of the Luckic et al. ring 18 incorporated into the Fiedler sheath 36) having a lubricious surface quality while the stent retraction portion of the

Fiedler sheath 36 would have a smooth inner surface of a second material (the polymeric material of the main portion of sheath 36 noting col. 7, lines 1-9 of Fiedler) different from the first material. Further, the inner surface of the Fiedler stent retention portion of the sheath 36 (including the Luckic et al. ring 18 incorporated therein) would be exposed to the stent containment sheath lumen as now claimed. The surface quality of the Luckic et al. ring 18 is inherently lubricious, to some extent, since it is smooth (as shown in the figure) and hard (since it is metal). As further evidence that the surface quality of metal is inherently lubricious, note that Mager et al. teach that the surface of metal is "slippery" and has a "low coefficient of friction" (col. 5, lines 5-7). Fiedler fails to disclose a "stent plunger" to provide a backing for the stent. However, Luckic et al. teach that a stent should be supported or backed by a rigid stop 37, 41 apparently in order to prevent it from migrating proximally within the sheath during sheath retraction as well as providing the advantage of preventing the stent from scratching the catheter (col. 7, line 61 to col. 8, line 16). It would have been obvious to include a rigid stop on the Fiedler catheter 22, separate from flexible seal 38, so that it too would have this advantage. As to the limitations in claim 1, lines 9-10, 13-14, 26 and 29-31 referring to a

compressed stent length, it is noted that the stent itself is not claimed. The Fiedler instrument is inherently capable of holding a stent which is shorter than the stent shown in the figures and thus meets these limitations in the claim.

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randall et al. (6,514,261). Randall et al. disclose a catheter having a guidewire lumen (col. 3, line 49), a stent retention section which extends (distally) from a stent plunger 28 which is fixed to the catheter (since it is fixed to spring 12 as indicated in col. 3, lines 58-60) and a sheath retraction section (the portion of tube 14 which extends proximally from plunger 28), stent containment sheath 10 and spacer 12 which is loosely contained within the stent containment sheath 10 and outside the sheath retraction section (since the sheath 10 can slide relative to spacer 12). Spacer 12 is inherently sized to substantially interfere with the kinking of the stent containment sheath when the stent containment sheath containing a portion of the catheter is bent since any kinking that sheath 10 experiences will be limited due to its contact with spacer 12 as the sheath is bent. Randall et al. fail to disclose a mount fixed to the catheter. However, it is old and well known to mount a radiopaque marker on a catheter in order to obtain the advantage of determining its position in

the body. It would have been obvious to mount a radiopaque marker on the Randall et al. catheter so that it too would have this advantage. The means which mounts the marker on the catheter would be the claimed mount. As to claim 30, spring 12 has a substantially planar coil shape since each winding of the coil lies substantially within a plane because each winding contacts the adjacent winding since the spring is fully compressed as indicated in col. 4, lines 40-43 and as shown in figure 1. As to claim 31, the thickness of the spring 12 tapers to a smaller thickness near its outer edge due to the round cross-section of the wire of the spring. As to claim 32, the windings of spring 12 are "stacked" rings since they abut one another along the length of the spring.

Claims 2-10,12-22 and 25-27 are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note col. 9, lines 17-21 of Mileo et al. (5,924,664) and col. 8, lines 16-17 of Bodicky (5,240,537).

Applicant's arguments filed August 24, 2005 have been fully considered but they are not persuasive. The claimed term "lubricious", simply means "slippery". Hard metal which is formed into a shape that has a smooth surface is inherently slippery so some extent. The specific coefficient of friction

of approximately 0.2 is not claimed. Luckic et al. teach that a stop 37, 41 for a stent should be shaped as shown in figure 5 (in which it surrounds and covers the proximal end of the stent) in order to obtain the advantage of preventing the stent from scratching the catheter (col. 7, line 61 to col. 8, line 16). This advantage is not present in the Fiedler instrument since the seal 38 of Fiedler which acts as a stop does not surround and cover the proximal end of the stent to prevent such scratching. It therefore would have been obvious to include a stop as shown in Luckic et al. in figure 5 on the Fiedler instrument so that it too would have this advantage. As to claims 28-32, spring 12 of Randall et al. is inherently an anti-kinking spacer since any kinking that sheath 10 experiences will be limited due to its contact with spacer 12 as the sheath is bent. The argument that no axial force is carried or transmitted by the spacer of applicant's invention is not persuasive since this feature is not claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can

be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
11/1/05

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731